Oral steroids for the treatment of inflammatory CRPS-1

No registrations found.

Ethical review Not applicable

Status Pending

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27326

Source

Nationaal Trial Register

Brief title

OSTIN

Health condition

complex regional pain syndrome type-1

Sponsors and support

Primary sponsor: NA

investigator initiated research

Source(s) of monetary or material Support: Stichting Esperance

Intervention

Outcome measures

Primary outcome

Primary Objective:

Assessment of a group difference in clinically important improvement in functional outcome of at least 10 points as measured by the DASH questionnaire

Secondary outcome

Secondary Objective(s):

- 1. To determine if there is a group difference in improvement in global perceive effect of therapy as measured on a 7 point scale
- 2. To determine if there is a group difference in improvement in pain intensity scores as measured by a pain diary three times daily during the week before each study visit.
- 3. To determine if there is a group difference in improvement in edema as measured by a measurement tape
- 4. To determine if there is a group difference in improvement in discoloration as measured on a 3 point scale
- 5. To determine if there is a group difference in cortisol levels of responders to treatment versus non responders. A responder is a subject who has at least 10 points improvement in the DASH questionnaire

Study description

Study objective

the active treatment group has an improvement of at least 10 points of DASH functional outcome more than the placebo group.

Study design

Follow up will be at 1, 3, 6, 9 and 12 months after randomization and start of treatment

Intervention

prednisolon versus placebo

Contacts

Public

Hilvarenbeekse weg 60

Yzabel Vandevivere Postbus 90151

Tilburg 5000 LC
The Netherlands
Scientific
Hilvarenbeekse weg 60

Yzabel Vandevivere Postbus 90151

Tilburg 5000 LC
The Netherlands

Eligibility criteria

Inclusion criteria

- 1. CRPS-1 (clinical Budapest criteria) in one arm only.
- 2. Inflammatory type: painful upper extremity, temperature difference, swelling, red discoloration, limited hand function.
- 3. Occurring after trauma or upper extremity surgery
- 4. Acute stadium of less than 12 months duration
- 5. Diminished functioning of the upper extremity as established by a DASH score of 10 or more (Hudak, 1996)
- 6. Average pain score of 3 or more on a one week pain diary, three times daily
- 7. No indication for surgical therapy or no future surgery planned
- 8. Age 18-80

Exclusion criteria

- 1. Not able to comply with follow up visits
 - 3 Oral steroids for the treatment of inflammatory CRPS-1 31-05-2025

- 2. < 18 or > 80 years of age
- 3. More than one extremity involved
- 4. Body temperature of ¡Ý 38 degrees Celsius
- 5. Elevated white blood cell count (> 10-E9 / liter)
- 6. Elevated BSE or CRP
- 7. Associated Infectious disease
- 8. Peptic ulcer
- 9. Pregnancy
- 10. Coagulation disorders, use of anticoagulants
- 11. Untreated hypertension
- 12. Untreated diabetes
- 13. Untreated cardiac failure
- 14. Current steroid use
- 15. Liver or kidney failure

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

Control: Placebo

Recruitment

NL

Recruitment status: Pending

4 - Oral steroids for the treatment of inflammatory CRPS-1 31-05-2025

Start date (anticipated): 01-10-2015

Enrollment: 52

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL5261 NTR-old NTR5377

CCMO NL-OSTIN 2015-003

Study results